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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/049,904      | 02/20/2002  | Hiroyuki Miyachi     | 219217US0PCT        | 2368             |

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EXAMINER

ANDERSON, REBECCA L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 08/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/049,904

Applicant(s)

MIYACHI ET AL.

Examiner

Rebecca L Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-10 are currently pending

#### ***Claim Objections***

Claims 8-10 are objected to for being substantial duplicates of claim 1. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. M.P.E.P. 706.03(k). In the instant claims, it appears that the claims mentioned supra are intended to claim the method of use for the compound of formula I or its pharmaceutical composition: as a "blood glucose-decreasing drug" (claim 8); a "lipid in blood-decreasing drug" (claim 9); and "an agonist drug of human peroxisome proliferator-activated receptor" (claim 10). This objection can be overcome by deleting the duplicate claims, or by amending the claims to be correct methods of use claims including positive method steps.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, since claim 1 contains parenthetical marks, rendering each of the claims indefinite because it is unclear what exactly applicant

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means to claim as the invention. This rejection can be overcome by deleting the parentheses from claim 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,061,717 and EP 0 846 693.

The claims at issue teach benzylthiazolidine-2,4-dione products of the formula (1) as found in claim 1 wherein A denotes a phenyl, phenoxy, or benzyloxy group. These products can be used as blood glucose-decreasing drugs, lipid in blood-decreasing drugs and as agonists of human peroxisome proliferator-activated receptors for the treatment of diabetes and hyperlipidemia.

***Determining the scope and contents of the prior art.***

US Patent No. 5061717 discloses thiazolidinedione compounds of the formula (I) wherein X1 and X2 can be hydrogen, methyl, trifluoromethyl, **phenyl**, benzyl, hydroxy, methoxy, **phenoxy**, **benzyloxy**, etc. (column 3 lines 60-67 and column 4 lines 1-21). X2 is preferably hydrogen, and X2 is preferably hydrogen, 2-methoxy, 4-benzyloxy or 4-phenyl. A and B can be CH or N, preferably CH. X can be S, SO, CH2, CO, preferably CO. Z can be CHR3, Y can be NR2, n can be 1, and R is preferably hydrogen and the dotted line represents no bond (column 4, lines 1-27). These compounds are useful as blood glucose lowering compounds for the treatment of hyerglycemia (column 4, lines 50-63). US Patent No. 5061717 furthermore discloses specific compounds in the table found on column 19 wherein X2 is benzyloxy (#46) and phenyl (#48b), and US Patent NO. 5061717 discloses the specific compound of example #75 on column 24 wherein X2 is phenoxy.

EP 0 846 693 discloses benzyldioxothiazolidylbenzamide compounds of the formula (I) which are useful for the treatment of diabetes and hyperlipidemia (page 2,

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lines 1-6). The compound of formula (I) is substituted by R1, R2 and R3. R1 and R2 can be hydrogen, lower alkyl, lower alkoxy, lower haloalkyl, etc., while R3 can be lower alkoxy, hydroxyl or halogen atom. The dotted line indicated a double or a single bond (page 2 lines 30-46). Furthermore, EP 0 846 693 discloses specific compounds wherein the dotted line is a single bond, and R3 is **methoxy** (compound examples 15, 17, 19, 22 and 26 in Table 5, pages 12-13).

***Ascertaining the differences between the prior art and the claims at issue.***

The difference between the prior art of US Patent No. 5061717 and the claims at issue is that there is no methoxy substituent on the benzamide ring.

The difference between the prior art of EP 0 846 693 and the claims at issue is that in the position equivalent to applicant's substituent A, the prior art does not have phenyl, phenoxy, or benzyloxy.

***Resolving the level of ordinary skill in the pertinent art.***

However, minus the showing of unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention when faced with US Patent No. 5061717 and EP 0 846 693 to create products which are useful for the treatment of diabetes and as glucose lowering drugs due to the similar chemical structure (benzyldioxothiazolidylbenzamide) of the compounds of the prior art and their uses for the treatment of diabetes and as a glucose lowering drug. The reasoning behind the finding of obviousness is that EP 0 846 693 discloses compounds in which the basic structure common to US Patent No. 5061717 (i.e. benzyldioxothiazolidylbenzamide) can be substituted by methoxy and is useful as for the treatment of diabetes. Consequently, the motivation to prepare compounds as found in US Patent NO. 5061717 substituted

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by methoxy would be to create other useful benzyldioxothiazolidylbenzamide compounds useful as blood glucose lowering drugs.

### Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703) 605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.


If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.



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